K052135

CYBERSONICS

DEC 2 0 2005

510(k) Summary per 807.92(c)
for
Cybersonics, Inc.

CYBERWAND DUAL PROBE LITHOTRIPTER

SPONSOR

CYBERSONICS, INC.
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Contact Person: William A. Stoll
Date Prepared: August 01, 2005

DEVICE NAME

Trade/Proprietary Name: Cybersonics, Cyberwand Dual Probe Lithotripter
Common/Usual Name: Intracorporeal ultrasonic lithotripter
Classification Name: Lithotripter, Ultrasonic
Class: II (876.4480) 78 FFK

DEVICE EQUIVALENCE

Substantially equivalent to the legally marketed **EMS Swiss Lithoclast Ultra**.

DEVICE DESCRIPTION

The Cybersonics, Cyberwand Dual Probe Ultrasonic Lithotripsy system is an electromechanical device capable of fragmenting and aspirating calculi. The hand piece consists of an ultrasonic transducer containing the piezo-electronic elements, which are driven by a generator operating at 21 ± 1 kHz. The resulting longitudinal waves are propagated along the ultrasonic dual probe to the target stone. The ultrasonic transducer probes are hollow, permitting simultaneous suction.

INTENDED USE

The Cybersonics, Cyberwand Dual Probe Lithotripter is intended to be used for the percutaneous fragmentation and removal of kidney stones.

BASIS FOR SUBSTANTIAL EQUIVALENCE

Cybersonics Cyberwand Dual Probe Lithotripter is substantially equivalent to the Electro Medical Systems SA Swiss LithoClast Ultra (K012445), and Karl Storz Calcuson Ultrasonic Lithotripter (K973251) which have been cleared for the percutaneous fragmentation and removal of kidney stones. Information on these systems can be found in section 11 of this submission. The Cyberwand Dual Probe Lithotripter has similar intended use and technical specifications as compared with the predicate devices. Substantial equivalence has also been demonstrated by stone fragmentation testing. These tests confirmed that the Cybersonics, Cyberwand Dual Probe Lithotripter results in fragmentation of a variety of standard artificial stone materials (ranging from soft to hard) when tested against predicate ultrasound lithotripters.

Comparison of Technological Characteristics

	Storz Calcuson	Olympus LUS-2	EMS LithoClast Ultra	Cybersonics Cyberwand
Operating Frequency	25--26kHz	23.5kHz	24—26kHz	20—22kHz
Utilities	120--240 Vac	120--240 Vac	120--240 Vac	120--240Vac
Autoclavable probes and hand piece	Yes	Yes	Yes	Yes
Probes threaded for assembly	Yes	Yes	Yes	Yes
Probe length (standard)	400 mm	400 mm	400 mm	400 mm
Probe OD ≤ 3.75mm	Yes	Yes	Yes	Yes
Ultrasonic Probe tip excursion ≤100 µm	Yes	Yes	Yes	Yes
Detachable hand piece	Yes	Yes	Yes	Yes
Handpiece with rear suction connection	Yes	Yes	Yes	Yes
Piezo stack with Titanium horn	Yes	Yes	Yes	Yes
Detachable footswitch	Yes	Yes	Yes	Yes
Table Top Generator	Yes	Yes	Yes	Yes
Applied Part BF	Yes	Yes	Yes	Yes

Drill Rate Comparisons Drill rate data supplied by Indiana University School of Medicine		
Instrument	**Stones Treated**	**Drill Rate in Seconds (Mean +/- SD)**
Cyberwand	10	8.7 +/- 0.9
Litho Clast Ultra	10	10.9 +/- 1.0
Olympus LUS-2	25	28.8 +/- 2.7
Circon-ACMI USL-2000	25	31.7 +/- 8.1
Karl Storz Calcuson	15	40.3 +/- 8.1
Olympus LUS-1	12	60.5 +/- 13.5
Richard Wolf Model 2271-004	10	103.7 +/- 21.6

CONCLUSION

Cybersonics Cyberwand Dual Probe Lithotripter is substantially equivalent to the legally marketed devices compared herein. Further, the Cyberwand is as safe, as effective and performs as well or better than the predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2005

Mr. William A. Stoll
Manager of Quality Assurance & Regulatory Affairs
Cybersonics, Inc.
5368 Kuhl Road
ERIE PA 16510

Re: K052135
Trade/Device Name: Cyberwand Dual Probe Lithotripter
Regulation Number: 21 CFR §876.4480
Regulation Name: Electrohydraulic lithotriptor
Regulatory Class: II
Product Code: FFK
Dated: November 29, 2005
Received: November 30, 2005

Dear Mr. Stoll

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052135

Device Name: Cybersonics – Cyberwand Dual Probe Lithotripter

Indications for Use:

The Cyberwand Dual Probe Lithotripter is intended to be used for the fragmentation of urinary tract calculi in the kidney, ureter, and bladder.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052135

(Posted November 13, 2003)